K121801



**B. 510(k) SUMMARY (as required by 21 CFR 807.92)**

**Quintex Cervical Plating System**
August 20, 2012

SEP 11 2012

**COMPANY:** Aesculap Implant Systems, Inc.
3773 Corporate Parkway
Center Valley, PA 18034
Establishment Registration Number: 3005673311

**CONTACT:** Lisa M. Boyle
800-258-1946 (phone)
610-791-6882 (fax)

**TRADE NAME:** Quintex Cervical Plating System

**COMMON NAME:** Anterior Cervical Screw Spinal Fixation System

**CLASSIFICATION NAME:** Spinal Intervertebral Body Fixation Orthosis (87KWQ)

**REGULATION NUMBER:** 888.3060

**PURPOSE FOR PREMARKET NOTIFICATION**
The Quintex Cervical Plating System described in this submission represents minor changes implemented to the Quintex screw and screwdriver.

**SUBSTANTIAL EQUIVALENCE**
Aesculap Implant Systems (AIS), Inc., believes that the modifications to Quintex Cervical Plating System is substantially equivalent to the AIS Quintex Cervical Plating System (K100243).

**DEVICE DESCRIPTION**
The Aesculap Implant Systems (AIS) Quintex Cervical Plating System consists of dynamic and semi-constrained plate, screws and associated instruments. Fixation is provided by bone screws inserted into the vertebral body of the cervical spine using an anterior approach. The AIS Cervical Plating System is manufactured from Titanium Alloy/Phynox and will be provided non-sterile.

**INDICATIONS FOR USE**
The Quintex Cervical Plating System is intended for the treatment of cervical spinal instability resulting from:

- Degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies),
- Spondylolisthesis,
- Trauma (i.e. fracture or dislocation),

- Spinal Stenosis,
- Deformity (i.e., scoliosis, kyphosis, and/or lordosis),
- Tumors,
- Pseudoarthrosis as a result of failed spine surgery,
- Failed previous fusions,
- Symptomatic cervical spondylosis,
- Instability following surgery for the above indications.

Levels of anterior cervical intervertebral body screw fixation for this indication are from $C_2$-$T_1$.

Warning: This device is not approved or intended for screw attachment of fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

**TECHNOLOGICAL CHARACTERISTICS (compared to Predicate(s))**

The AIS Quintex Cervical Plating System remains substantially equivalent to current Quintex Cervical Plating System (K100243). Biomechanical testing of the subject device was found to be similar in performance to previously cleared system.

**PERFORMANCE DATA**

As recommended by the FDA Guidance for Spinal System 510(k)'s, non-clinical testing was performed to demonstrate the Quintex Cervical Plaing System is substantially equivalent to the predicate device. The following testing was performed:

- Off axis screw insertion
- Redirection of screw trajectory
- Intentional Pry Out

The results of these tests showed that the subject device meets or exceed the performance of the predicate device, and the device is therefore found to be substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Aesculap Implant Systems, LLC.
% Ms. Lisa Boyle
Senior Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

SEP 11 2012

Re: K121801
Trade/Device Name: Quintex Cervical Plating System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: August 24, 2012
Received: August 27, 2012

Dear Ms. Boyle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## A. INDICATIONS FOR USE STATEMENT

**510(k) Number:** K121801

**Device Name: Quintex Cervical Plating System**

**Indications for Use:**

The Quintex Cervical Plating System is intended for the treatment of cervical spinal instability resulting from:

- Degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies),
- Spondylolisthesis,
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Warning: This device is not approved or intended for screw attachment of fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Prescription Use X and/or Over-the-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices